

REMARKS

STATUS OF THE CLAIMS.

Claims 45-70 and 74-76 are pending with entry of this amendment, claims 71-73 and 77-86 being canceled herein. Claims 45-67 are allowed. Claim 68 is amended herein. These amendments introduce no new matter.

Under 37 C.F.R. § 1.116, amendments cancelling claims may be entered after final rejection. In addition, § 1.116 states that amendments to the claims after final rejection may be entered if the amendments place the claims in better form for consideration on appeal. Applicants submit that the above amendments meet this criterion. The amendment to claim 68 revises the phrase "about position q22 to about position q24" to read "position q22 to position q24." (In the previous Amendment, which was denied entry, Applicants sought to amend this phrase to recite "position q22 to about position q24;" *i.e.*, deleting only the first occurrence of the word "about.")

In the Advisory Action, the Examiner stated:

The amendment deletes the "about" before q22 but leaves the "about" before q24. This not only would require a further search and consideration with regard to the newly adjusted scope of the claim, but also raises questions about the metes and bounds of the claims.

Accordingly, the amendment to claim 68 is necessary to address the Examiner's concerns regarding the metes and bounds of the claims. The amendments were not presented earlier because the need for the amendments was not apparent until the Final Office Action and the Advisory Action were received. Entry of the amendments is thus permitted under § 1.116 and is respectfully requested.

RESTRICTION/ELECTION.

Pursuant to a restriction/election requirement, Applicants cancel claims 71-73 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and that the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Final Office Action.

35 U.S.C. §102.

Claims 68, 69, 71, and 74 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Tsuda et al. (Cancer Research (1989) 49:3104-3108). Final Office Action, page 1. This rejection moot as to canceled claim 71 and is respectfully traversed with respect to claim 68, 69, and 74.

Of the rejected claims, only claim 68 is independent. Claim 68 relates to a “method for detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences at “position q22 to position q24” on chromosome 17. Detection is carried out by hybridizing a suitable probe to the sample and detecting the hybridization complex.

In the Final Office Action, the Examiner stated: “Tsuda teaches [a] method for detecting a copy number variation in a suspected breast cancer sample . . . by detecting an amplification or gain of unique sequences . . . on chromosome 17, about position q22 to about position q24.” Final Office Action, pages 1-2. More specifically, the Examiner believed that Tsuda teaches the region “about position q22 to about position q24” because, according to the Examiner, Tsuda teaches that amplification ““of c-erbB2 was confirmed to be a factor indicating a poorer prognosis in breast carcinoma patients’, also see figure 1, case A, where ear1 at position 17q21-22 is amplified.” *Id.* The Examiner also cited page 3104, column 2, which states that “c-erbB-2 and one of the v-erbA-related genes, ear-1 are localized on chromosomes 17q21 and 17q21-22, respectively.” *Id.*

Claim 68 recites the detection of an amplification at the chromosomal region “on chromosome 17, position q22 to position q24.” This region clearly excludes the locus at 17q21.1, regardless of whether that locus is c-erbB-2 or something else.

A second gene that Tsuda disclosed as being amplified in breast cancer is ear-1, which Tsuda stated is at 17q21-q22. To be more precise, ear-1 is located at 17q21.1, as evidenced by Exhibits B and C, which accompanied the Amendment dated November 12, 2003. Applicants submit that “17q22 to 17q24” clearly distinguishes “17q21.1.” As Tsuda fails to teach this element of claim 68, Tsuda does not anticipate the claimed method. Claims 69 and 74 depend from claim 68 and are therefore novel over Tsuda for at least the same reason.

35 U.S.C. §103(A).

Claims 70, 75, and 76 were rejected under 35 U.S.C. § 103(a) as allegedly obvious in light of Tsuda in view of Mullis *et al.* (U.S. Patent No. 4,683,202) Final Office Action, page 3. This rejection is respectfully traversed.

Claims 70, 75, and 76 depend from claim 68 and therefore incorporate the element of detecting an amplification at 17q22 to 17q24. The Examiner contended that Tsuda teaches the detection of amplifications in this region. However, as pointed out above, Tsuda teaches amplifications at either 17q11-12 or 17q21 (c-erbB-2; as noted previously, there is some confusion in the literature over the location of this gene) and 17q21.1 (ear-1), not at 17q22 to 17q24.

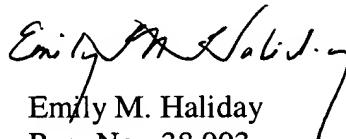
Mullis does nothing to remedy this deficiency. Mullis is cited as teaching the elements recited in claims 70, 75, and 76, namely labeling the sample nucleic acid (claim 70), using amplified DNA as the sample nucleic acid (claim 75), and using cDNA as the sample nucleic acid (claim 76). *See* Final Office Action, page 3. Mullis neither teaches nor suggests anything about detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences at "on chromosome 17, position q22 to position q24," as recited in claim 68 and incorporated into dependent claims 70, 75, and 76. Thus, the Tsuda-Mullis combination fails to teach or suggest all of the elements of rejected claims 70, 75, and 76. Withdrawal of the § 103 rejection of these claims over Tsuda and Mullis is therefore respectfully requested.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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Respectfully submitted,


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